



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,972	03/30/2004	Chris Lee	21684/1211620-US2	8626
85729 7590 03/02/2010 Boston Scientific Neuromodulation (SVI & JHU) c/o Darby & Darby P.C. P.O. Box 770 Church Street Station New York, NY 10008-0770			EXAMINER LUONG, PETER	
			ART UNIT 3737	PAPER NUMBER
			MAIL DATE 03/02/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 9-12, 16-18, 20, 26, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by McKinnon (US 5,792,055).

3. With respect to claims 1-4, 9-12, 16-18, 20, 26, and 47 the patent of McKinnon discloses a MRI guidewire (abstract) comprising an inner conductor (13, i.e. center conductor), an outer conductor (15), a distal end sized and shaped for insertion into a subject to receive MRI signals (fig 1), a proximal end sized and shaped for insertion into a connector (col. 4, lines 54-65; see fig 1, it is inherent for a connection means to connect the guidewire to the control station), an insulated area between the outer and inner conductor (14), and the guidewire is connected to the MRI scanner and MRI circuits (fig. 1). With respect to the inner and outer conductor contacts, the Examiner interprets the surface of the inner and outer conductors to be the contacts as any conductive material touching the surface of the conductor would be electrically coupled to the conductor. McKinnon discloses the inner conductor extending beyond the outer conductor (col. 4, ln. 57-65, col. 4, line 66 to col. 5, line 27; figs. 1-3). With respect to claim 16, the Examiner notes that any material can be made sterilizable. With respect to claim 22, McKinnon discloses an extension attachment at the proximal end of the

guidewire (col. 5, ln. 7-9). With respect to claim 47, McKinnon discloses the contacts having approximately the same diameter (see Figs. 2 and 3).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 25, 33, 38, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKinnon (US 5,792,055).

7. With respect to claim 25, McKinnon discloses the subject matter substantially as claimed except for wherein the inner conductor contact and the inner conductor define a diameter that is greater than a diameter of the inner conductor extending along the outer conductor. However, it is obvious to one of ordinary skill in the art to change the

size of the diameter of the inner/outer conductors and contacts as the change in size is well within the skill level of one of ordinary skill in the art.

8. With respect to claim 38, the Examiner notes that any device can be disposed of after a single-use.

9. Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKinnon (US 5,792,055) as applied to claim 1, further in view of Glowinski et al. (US 5,868,674).

10. The patent of McKinnon discloses the subject matter substantially as claimed except for wherein the guidewire diameter is between about 0.012 inches and 0.038 inches and an inner conductor diameter to be between about 0.004 inches and about 0.012 inches.

11. However, Glowinski et al. teaches a MRI catheter with a diameter between 0.3 mm (0.0118 inches) to 3 mm (0.118 inches) for insertion into a patient (fig. 1).

12. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the guidewire diameter to be about 0.012 inches and 0.038 inches as a change in size is within the skill level of one of ordinary skill in the art. Furthermore, it would have been obvious for the inner conductor to be smaller than the guidewire.

13. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKinnon (US 5,792,055) as applied to claim 1, further in view of Lardo et al. (US 6,675,033).

Art Unit: 3737

14. With respect to claims 13-15, the patent of McKinnon discloses the subject matter substantially as claimed except for wherein the guidewire comprises titanium or nitinol.

15. However, Lardo et al. teaches a MRI guidewire probe comprising known super-elastic material comprising titanium and nitinol (col. 9, lines 25-50).

16. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the super-elastic material as taught by Lardo et al. those materials are known for their high biocompatibility (col. 9, lines 32-35).

17. Claims 22, 24, 27-28, 31, 34-36, and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKinnon (US 5,792,055) in view of Lardo et al. (US 6,675,033).

18. With respect to claims 22, 27-28, 31, 34-36, and 45, the patent of McKinnon discloses a MRI guidewire (abstract) comprising an inner conductor (13, i.e. center conductor), an outer conductor (15), a distal end sized and shaped for insertion into a subject to receive MRI signals (fig 1), a proximal end sized and shaped for insertion into a connector (col. 4, lines 54-65; see fig 1, it is inherent for a connection means to connect the guidewire to the control station), an insulated area between the outer and inner conductor (14), and the guidewire is connected to the MRI scanner and MRI circuits (fig. 1). With respect to the inner and outer conductor contacts, the Examiner interprets the surface of the inner and outer conductors to be the contacts as any conductive material touching the surface of the conductor would be electrically coupled to the conductor. McKinnon discloses the inner conductor extending beyond the outer

conductor (col. 4, ln. 57-65). (col. 4, line 66 to col. 5, line 27; figs. 1-3). With respect to claim 22, McKinnon discloses an extension attachment at the proximal end of the guidewire (col. 5, ln. 7-9).

19. McKinnon does not teach a connector, however, Lardo et al. teaches MRI guidewires releasably attachable to connectors. Lardo et al. teaches wherein all the components are non-magnetic (col. 14, lines 57-58). Lardo et al. teaches various sizes and shapes of the connectors (see figures). Lardo et al. teaches an interfacing circuit (fig. 26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided McKinnon with connectors as taught by Lardo et al. in order facilitate connecting to interface circuitry to be connected to the MRI scanner (col. 11, lines 4-6).

20. With respect to claim 24, McKinnon discloses the subject matter substantially as claimed except for wherein the connector includes a wiper to inhibit the introduction of fluids into the connector. However, it is obvious to one of ordinary skill in the art to provide the connections between the guidewire and electronic circuitry with seals to prevent fluid contact as the intended use of a guidewire is to be inserted into a patient.

21. With respect to claim 46, McKinnon discloses the subject matter substantially as claimed except for wherein the inner conductor contact and the inner conductor define a diameter that is greater than a diameter of the inner conductor extending along the outer conductor. However, it is obvious to one of ordinary skill in the art to change the size of the diameter of the inner/outer conductors and contacts as the change in size is well within the skill level of one of ordinary skill in the art.

22. Claims 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over McKinnon (US 5,792,055) in view of Lardo et al. (US 6,675,033) as applied to claim 45, further in view of Wiener et al. (US 7,273,483).

23. McKinnon discloses the subject matter substantially as claimed except for a guidewire sensor. However, Wiener et al. teaches in medical devices in which comprises releasable components for handpiece, blades, and shears to have unique identification numbers registered and stored in memory. Wiener et al. teaches the ID allows the system to acknowledge their compatibility and usability of each individual piece. (col. 13, lines 24-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided McKinnon with the unique ID system of Wiener et al. in order to allow the system to acknowledge the compatibility and useability of each component of guidewire and connector.

Response to Arguments

Applicant's arguments filed 12/16/2009 have been fully considered but they are not persuasive.

Applicant argues McKinnon does not teach the inner conductor extends beyond the outer conductor at the proximal end. However, the Examiner respectfully disagrees with the applicant. McKinnon discloses the outer conductor and insulator may be removed to the proximal end of the guidewire (col. 5, lines 10-16). The Examiner notes that the Applicant has failed to clearly define the "proximal end" and points out to the applicant that "removed to the proximal end" is still interpreted to be "at the proximal end" as "removed to the proximal end" requires that it reaches the proximal end.

Furthermore, the Examiner notes that as McKinnon teaches a “male connector” end, the process of attaching a coaxial connector requires the outer layer to be stripped from the inner layer in order to expose the inner conductor, in which the Examiner interprets to be the extended section.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Luong whose telephone number is (571)270-1609. The examiner can normally be reached on Monday - Friday, 9:30 a.m. - 6:00 p.m., EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art
Unit 3737

/P. L./
Examiner, Art Unit 3737